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VIBRANT AMERICA, LLC

13 **UNITED STATES DISTRICT COURT**
14 **NORTHERN DISTRICT OF CALIFORNIA**
15 **SAN FRANCISCO DIVISION**

16 UNITED STATES OF AMERICA ex rel. STF,
LLC, an organization; STATE OF
17 CALIFORNIA ex rel. STF, LLC, an
organization,,
18

Plaintiff,

19 vs.
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21 VIBRANT AMERICA, LLC, a Delaware
Limited Liability Company,
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Defendant.
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Case No. 3:16-cv-02487-JCS

**VIBRANT AMERICA LLC'S ANSWER TO
FIRST AMENDED COMPLAINT**

DEMAND FOR JURY TRIAL

Defendant Vibrant America, LLC (“Vibrant”), by counsel, respectfully states as follows for its Answer and Affirmative Defenses to the First Amended Complaint (Dkt. 75). The allegations in the First Amended Complaint are denied except to the extent they are expressly admitted below.

I. INTRODUCTION

1. **VIBRANT AMERICA, LLC (“VIBRANT” or “Defendant”) is perpetrating a fraud on U.S. and California taxpayers through two related kickback schemes designed to defraud Medicare, Medicaid, and private health insurers.**

ANSWER:

Denied.

2. **In one of its kickback schemes, VIBRANT enters into sham phlebotomy contracts with physicians’ family members and staff members in order to induce physicians to refer their Medicare and Medicaid laboratory business to VIBRANT and to generally order excessive numbers of tests for both Medicare, Medicaid, and privately insured patients. VIBRANT then pays kickbacks to physicians’ family or staff members in the form of well above market and unlawful “Process and Handling” and “Collection” fees (collectively referred to herein as “draw fees”) for each blood specimen physicians send to VIBRANT. VIBRANT pays these draw fees to whomever it enters into the sham contract with, whether or not that person actually performs blood draws or is a licensed phlebotomist.**

ANSWER:

Denied.

3. **In short, the physician or the physician’s staff member performs a blood draw at the physician’s office and then ships the sample to VIBRANT’s lab in San Carlos, California. The test is performed at the lab, and the test results are reported to the physician. In exchange the physician’s family member or staff member receives a \$15 payment per patient for “processing and handling services” related to the blood sample. These practices constitute an illegal kickback scheme, no more legal than if Defendant simply handed physicians envelopes of cash in exchange for Medicare,**

1 **Medicaid, and other referrals.**

2 **ANSWER:**

3 Vibrant admits physician staff members independently contracted by Vibrant perform certain
4 services for Vibrant including phlebotomy services, and that Vibrant performs tests on blood samples at
5 its lab in San Carlos, California and subsequently reports test results to physicians. Vibrant denies the
6 remaining allegations in Paragraph 3.

7 **4. In another related kickback scheme, VIBRANT promises to cap patient deductible**
8 **and/or co-payments at \$25 for physicians' privately insured patients. This \$25 cap is**
9 **of great value and benefit to physicians because it allows them to attract and retain**
10 **patients by promising to perform all lab testing for no more than \$25. Additionally,**
11 **VIRBARNT [sic.] promises physicians that it will never send patients to collections**
12 **for failure to pay the \$25 deductible or co-payment.**

13 **ANSWER:**

14 Denied.

15 **5. VIBRANT's waiver of deductibles and co-payments and its payment of draw fees**
16 **constitutes illegal remuneration, designed to: (1) "pull through" higher-paying**
17 **Medicare and Medicaid business to Defendant, (2) entice Medicare, Medicaid, and**
18 **privately insured patients to seek treatment from and/or continue to receive**
19 **treatment from physicians whose family and staff members have illegal kickback**
20 **arrangements with VIBRANT, and (3) induce physicians to order excessive numbers**
21 **of tests from VIBRANT for their Medicare, Medicaid, and privately insured patients.**

22 **ANSWER:**

23 Denied.

24 **6. Additionally, some TRICARE options require participating members to pay a co- pay**
25 **and/or meet a deductible amount. 32 C.F.R. § 199.4(f). A provider of services cannot,**
26 **as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R. §**
27 **199.4(f)(9). Accordingly, VIBRANT's waiver of deductibles and co-pays causes the**
28 **submission of false claims for tests performed on TRICARE patients as well.**

Furthermore, waiving insurance co-payments is explicitly illegal under the laws of several states.

ANSWER:

Vibrant denies the allegations in the third sentence (excluding citation sentences as sentences) of Paragraph 6. The remaining allegations in Paragraph 6 are legal conclusions to which no response is required. To the extent a further response is required, Vibrant denies the allegations in Paragraph 6 to the extent they are inconsistent with the text of, or are Relator's interpretation of, the TRICARE program and the regulations cited in Paragraph 6, or are incomplete recitations of such law.

7. This is a *qui tam* action for violation of the federal False Claims Act (31 U.S.C. §§ 3150 et seq.) and the California False Claims Act (Cal. Gov. Code §§ 12650 et seq.) to recover treble damages, civil penalties and attorneys' fees and costs for Plaintiffs and on behalf of the United States, and California for fraudulent Medicare and Medicaid. Non-public information personally known to Relator STF, LLC ("STF") serves as the basis for this action. Defendant's schemes have also caused private insurers in California to be charged for tests performed on patients procured and/or retained via illegal kickbacks. Accordingly, Relator brings claims under California Insurance Code §1871.7, *et seq.*, to recover fraudulent charges on behalf of the California Department of Insurance.

ANSWER:

Vibrant admits that Relator purports to bring an action under the False Claims Act ("FCA"), California False Claims Act ("CFCA"), and California Insurance Frauds Prevention Act ("CIFPA"), but denies that Relator or the government is entitled to any relief whatsoever. Vibrant denies the remaining allegations of Paragraph 7.

II. JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 31 U.S.C. sections 3730(b) and 3732(a), which confer jurisdiction on this Court for actions brought under the federal False Claims Act, and authorize nationwide service of process. Venue is proper in this district pursuant to 31 U.S.C. section 3732(a), as VIBRANT's

laboratory is located in the Northern District of California.

ANSWER:

The allegations in Paragraph 8 are legal conclusions to which no response is required. To the extent a further response is required, Vibrant admits that this Court has subject matter jurisdiction over this matter and that venue is proper in this Court.

III. PARTIES

9. The plaintiffs in this action are the UNITED STATES OF AMERICA (“United States”), and the STATE OF CALIFORNIA (“California”), by and through Relator STF, LLC.

ANSWER:

Admitted.

10. Relator STF, LLC is a limited liability company, whose members are involved in the healthcare industry. STF, LLC is an “interested person” for purposes of the California Insurance Frauds Protections Act (“IFPA”), as it is in possession of nonpublic information of Vibrant’s wrongdoing, including, but not limited to, the information contained in paragraphs 32- 42, and 45-50 below, and in Exhibits A-E attached hereto. That nonpublic information was obtained by STF, LLC’s members, primarily directly from Vibrant’s employees.

ANSWER:

Vibrant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first and third sentences of Paragraph 10 and therefore denies the same. Further, Vibrant denies any wrongdoing by Vibrant. The remaining allegations in the second sentence of Paragraph 10 are legal conclusions to which no response is required. To the extent a further response is required, Vibrant denies the allegations in the second sentence of Paragraph 10.

11. Defendant VIBRANT AMERICA, LLC is a Delaware limited liability company with its principal places of business in San Carlos, California.

ANSWER:

Admitted.

IV. STATUTORY BACKGROUND

A. The Federal False Claims Act

12. The Federal False Claims Act (“FCA”), as amended by the Fraud Enforcement and Recovery Act of 2009 (“FERA”), Pub. L. 111-21, section 4(f), 123 Stat. 1617, 1625 (2009), provides in pertinent part that a person is liable to the United States government for three times the amount of damages the government sustains because of the act of that person, plus a civil penalty, for each instance in which the person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(1)(1)(A).

ANSWER:

The allegations in Paragraph 12 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 12 to the extent that they are inconsistent with the text of, or are Relator’s interpretation of, the False Claims Act, or are incomplete recitations of such law.

13. The FCA defines the term “claim” to mean “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be drawn down or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government (i) provides or has provided any portion of the money or property requested or demanded; or (ii) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.” 31 U.S.C. § 3729(b)(2)(A).

ANSWER:

The allegations in Paragraph 13 purport to refer to and quote text from the False Claims Act to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 13 to the extent that they are inconsistent with the text of, or are Relator’s interpretation of, the

False Claims Act, or are incomplete recitations of such law.

14. As amended by FERA, the FCA also makes a person liable to the United States government for three times the amount of damages which the government sustains because of the act of that person, plus a civil penalty, for each instance in which the person “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1)(B).

ANSWER:

The allegations in Paragraph 14 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 14 to the extent that they are inconsistent with the text of, or are Relator’s interpretation of, the False Claims Act, or are incomplete recitations of such law.

15. The FCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information: (1) “has actual knowledge of the information”; (2) “acts in deliberate ignorance of the truth or falsity of the information”; or (3) “acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). The FCA further provides that “no proof of specific intent to defraud” is required. 31 U.S.C. § 3729(b)(1)(B).

ANSWER:

The allegations in Paragraph 15 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 15 to the extent that they are inconsistent with the text of, or are Relator’s interpretation of, the False Claims Act, or are incomplete recitations of such law.

B. The Medicare Program

16. Medicare is administered by the United States government and provides health coverage to people 65 years of age and older. Medicare’s costs are staggering. In 2014, Medicare expenditures accounted for 14% of all federal spending.

ANSWER:

The allegations in Paragraph 16 constitute legal conclusions and characterizations to which no

response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 16 to the extent that they are inconsistent with, or are Relator's interpretation of, the Medicare Program and its costs.

17. To ensure taxpayers' dollars are funding truly necessary and appropriate medical treatment, Medicare providers are prohibited from submitting reimbursement claims for items and services neither reasonable nor necessary for the diagnosis or treatment of a Medicare patient. 42 U.S.C. § 1395y(a)(1)(A).

ANSWER:

The allegations in Paragraph 17 constitute legal conclusions and characterizations to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 17 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the Medicare Program and the statutes cited in Paragraph 17, or are incomplete recitations of such law.

18. Medicare, along with the Department of Health and Human Services have long prohibited providers from charging Medicare for services which are tainted by unlawful kickbacks. Unlawful kickback schemes are strictly prohibited by the Medicare statutes and give rise to False Claims Act liability.

ANSWER:

The allegations in Paragraph 18 constitute legal conclusions and characterizations to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 18.

19. The Affordable Care Act, passed in March 2010, made explicit that violations of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b) gave rise to False Claims Act liability: "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g).

ANSWER:

The allegations in Paragraph 19 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 19 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the False Claims Act, the Affordable Care

Act, or the Anti-Kickback Statute, or are incomplete recitations of such law.

20. Specifically, the Anti-Kickback Statute creates liability for “whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program. . . .” 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added).

ANSWER:

The allegations in Paragraph 20 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 20 to the extent that they are inconsistent with the text of, or are Relator’s interpretation of, the Anti-Kickback Statute, or are incomplete recitations of such law.

21. Interpretations of this language by the federal authorities provide useful guidance in applying anti-kickback laws. The Department of Health and Human Services, Office of the Inspector General (“OIG”) has issued various advisory opinions regarding indicia of illicit schemes that providers have employed to defraud Medicare.

ANSWER:

The allegations in Paragraph 21 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant admits that the Department of Health and Human Services, Office of the Inspector General (“OIG”), has issued various advisory opinions and denies the remaining allegations.

22. In June 2005, the OIG issued an Advisory Opinion concluding that payments by a laboratory to referring physicians of \$6 per day for “collection of blood samples,” likely constituted “prohibited remuneration under the anti-kickback statute.” OIG Advisory Opinion No. 05-08, at pp. 1-2, available <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0508.pdf>. Specifically, the OIG stated:

Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory Because the physicians would receive a portion of the Lab's reimbursement for blood tests resulting from the physicians' referrals, the physicians have a strong incentive to order more blood tests. As a result, there is a risk of overutilization and inappropriate higher costs to the Federal health care programs.

OIG Advisory Opinion No. 05-08, at p. 4 (emphasis added).

ANSWER:

The allegations in Paragraph 22 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 22 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the OIG Advisory Opinion No. 05-08, or are incomplete recitations of such opinion.

23. OIG Advisory Opinion No. 05-08 considered whether a laboratory's proposal to pay physicians for the collection of blood samples and to provide free blood drawing supplies would constitute grounds for imposition of sanctions due to violation of the Anti-Kickback Statute. HHS concluded such a structure gave rise to the inference that the payments were made in exchange for referrals because the offer carried a "substantial risk that the Lab would be offering the blood draw remuneration to the physicians in exchange for referrals . . . [and that] the compensation provides an obvious benefit to the referring physician." OIG Advisory Opinion No. 05-08 at 4.

ANSWER:

The allegations in Paragraph 23 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 23 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the OIG Advisory Opinion No. 05-08, or are incomplete recitations of such opinion.

24. Standard industry practice allows a laboratory to pay physicians and medical assistants a nominal fee for the small amount of time it takes to draw, collect and package a specimen. Medicare, for example, permits a \$3 per patient payment to physicians for drawing a patient's specimen. These "Specimen Processing Arrangements" must comply with the Anti-Kickback Statute such that physicians are not induced to order medically unnecessary and unreasonable tests in order to receive remuneration.

ANSWER:

The allegations in Paragraph 24 constitute legal conclusions and characterizations to which no response is required. To the extent a response is required, Vibrant denies the allegations, except admits that the reimbursement under the Medicare Fee Schedule for CPT Code 36415 (Routine Venipuncture) is \$3.

25. However, as stated by the OIG, when a laboratory pays a referring physician for performing blood draws, and the amount exceeds \$3, "an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory." OIG Advisory Opinion No. 05-08, p. 4; *see also* OIG Special Fraud Alert: Laboratory Payments to Referring Physicians, p. 4, n.10 (June 2014) ("2014 Special Fraud Alert").

ANSWER:

The allegations in Paragraph 25 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 25 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the OIG Advisory Opinion No. 05-08, OIG Special Fraud Alert: Laboratory Payments to Referring Physicians (June 2014) ("2014 Special Fraud Alert"), or are incomplete recitations of such opinion or alert.

26. The OIG's 2014 Special Fraud Alert described aspects of specimen processing arrangements that evidence unlawful practices. These aspects include: (1) payment that exceeds fair market value for services actually rendered by the party receiving the payment; (2) payment that is made directly to the ordering physician rather than

to the ordering physician's group practice, which bears the cost of collecting and processing the specimen; and (3) payment that is made on a per-test, per-patient, or other basis that takes into account the volume of referrals. See 2014 Special Fraud Alert, p. 4-5.

ANSWER:

The allegations in Paragraph 26 constitute legal conclusions and characterizations to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 26 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the 2014 Special Fraud Alert, or are incomplete recitations of such alert.

27. These statements are consistent with prior Advisory opinions, long notifying the industry that giving anything of value not paid for at fair market value gives rise to an inference that the gift is offered to induce business and is therefore a kickback. See OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (issued October 1994), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html> ("Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business.").

ANSWER:

The allegations in Paragraph 27 constitute legal conclusions and characterizations to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 27. Vibrant further denies the allegations in Paragraph 27 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994), or are incomplete recitations of such alert.

28. California law is equally clear. As stated in a recent Notice issued by the California Department of Public Health, the following scenario violates California's Anti-Kickback provision (Business and Professions Code § 650):

An employee of a physician is also paid by a laboratory as an "independent"

phlebotomist to collect specimens for the physician's patients. After the issuance of the federal OIG Special Fraud Alert issued June 25, 2014, a laboratory has changed its practices and now enters into a contractual arrangement directly with an individual, who is a member of a physician's office staff, to provide phlebotomy services to the laboratory. The individual provides the phlebotomy services on-site in the physician's office. The individual remains an employee of the physician's office and simultaneously receives payments directly from the laboratory as an independent contractor to the laboratory. In some circumstances the physician reduces the salary or compensation to that individual when such an arrangement is in place.

See <https://www.cdph.ca.gov/programs/lfs/Documents/CLTAC%20Non-Compliance%20Inducement%20letter.pdf> (last visited April 15, 2016).

ANSWER:

The allegations in Paragraph 28 constitute legal conclusions and characterizations to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 28 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, a notice issued by the California Department of Public Health, the CIFPA, or are incomplete recitations of such notice and law.

C. The California Insurance Frauds Protections Act

29. Additionally, pursuant to the California Insurance Frauds Protections Act ("IFPA"), which is located under section 1871.7(a) of the California Insurance Code, it is "unlawful to knowingly employ runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits . . . or to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis of a claim against an insured individual or his or her insurer." This provision has been construed as prohibiting charging private insurers for services procured via kickbacks.

ANSWER:

The allegations in Paragraph 29 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 29 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the California Insurance Frauds Protections Act, or are incomplete recitations of such law.

30. The IFPA allows members of the public to file private qui tam suits against anyone who commits insurance fraud in the state. Like the Federal and California False Claims Acts, any person or entity that violates the IFPA is subject to a civil penalty of up to \$10,000 for each claim submitted to an insurer for payment. The person or entity is also subject to treble damages for the amount of the claim for compensation billed to the insurer.

ANSWER:

The allegations in Paragraph 30 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 30 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the California Insurance Frauds Protections Act, or are incomplete recitations of such law.

31. Unlike the non-insurance-related false claims qui tam actions, under the IFPA it is not necessary that the government suffer harm as a result of the fraud. This is due to the fact that insurance fraud usually harms a large number of people, as insurance companies frequently cite insurance fraud losses in raising rates for policyholders. (For example, the IFPA states that healthcare insurance fraud likely increases national healthcare costs by "billions of dollars annually.") Thus, individuals who sue fraudulent actors under the IFPA are acting on behalf of themselves and every one of their fellow policyholders as well as for the State of California.

ANSWER:

The allegations in Paragraph 31 constitute legal conclusions and characterizations to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 31 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the California

Insurance Frauds Protections Act, or are incomplete recitations of such law.

V. VIBRANT KNOWINGLY VIOLATED THE FEDERAL AND CALIFORNIA FALSE CLAIMS ACTS THROUGH AN ILLEGAL KICKBACK SCHEME

32. VIBRANT, to induce physicians to order laboratory tests from its laboratory, enters into sham phlebotomy contracts with physician offices. VIBRANT Sales Representatives contact physicians with offers to make the physicians' family members or staff members "independent contractors" of VIBRANT. Specifically, physicians are told that their relatives and staff members can enter into sham contracts with VIBRANT, whereby the family member or staff member is deemed an "independent contractor." VIBRANT then pays the family member or staff member a separate \$15 draw fee for each blood specimen drawn and submitted to VIBRANT for testing. This is a sham designed to provide remuneration to physicians in exchange for laboratory test orders.

ANSWER:

Denied.

33. VIBRANT pays the \$15 draw fee irrespective of who actually performs the blood draw. For example, in or about December 2015, VIBRANT pitched its scheme to a California physician (who is one of STF, LLC's members). When the physician indicated that they did not have staff in the office who would be appropriate to serve as an "independent contractor" phlebotomist, VIBRANT suggested that a family member of the physician sign up as an "independent contractor," thereby allowing the physician to receive the draw fees. VIBRANT recommended to the physician that it be a family member with a different last name, so as not to raise suspicions. VIBRANT ultimately signed an "independent contractor" agreement with the physician's spouse, who has a different last name and is not a licensed phlebotomist.

ANSWER:

Vibrant admits that it entered into an independent contractor agreement with a member of STF, LLC's spouse and that the spouse has a different last name than the member of STF, LLC. Vibrant denies

the remaining allegations in Paragraph 33.

34. This arrangement allows the physician or their medical staff to supplement their income. By ordering tests through VIBRANT, physicians are able to direct cash to a family member or pay their staff less, appease their staff, and in some instances, obtain a portion of the medical staff's kickback.

ANSWER:

Denied.

35. VIBRANT's scheme is a deliberate violation of anti-kickback statutes.

ANSWER:

Denied.

36. Relator is in possession of direct, nonpublic evidence of VIBRANT's scheme. Attached hereto as Exhibit A is VIBRANT's standard "Phlebotomy Consulting Agreement" ("Consulting Agreement") through which it establishes a sham independent contractor arrangement with physicians' family members or office staff.

ANSWER:

Vibrant admits that Exhibit A is a copy of the Vibrant "Phlebotomy Consulting Agreement" that was used at Vibrant for a period of time. Vibrant denies the remaining allegations in Paragraph 36.

37. Attached hereto as Exhibit B is VIBRANT's standard "Phlebotomy Services Agreement" ("Services Agreement"), which describes the \$15 fee VIBRANT pays to the physicians' family member or staff member. VIBRANT describes the \$15 fee as a "Process and Handling Fee" and a "Collection Fee."

ANSWER:

Vibrant denies that Exhibit B is Vibrant's "standard 'Phlebotomy Services Agreement'" and states that Exhibit B contains incomplete copies of two different Vibrant Agreements each called a "Phlebotomy Services Agreement." The remaining allegations in Paragraph 37 purport to quote from or characterize one or both of the incomplete Phlebotomy Service Agreements provided at Exhibit B, to which no response is required. To the extent further response is required, Vibrant denies the remaining allegations in Paragraph 37 to the extent that Relator's references to either of the Phlebotomy Services Agreements

in Exhibit B are inconsistent with the text of or are Relator's interpretation of the Phlebotomy Services Agreements.

38. Attached hereto as Exhibit C is a check from VIBRANT to the family-member of the aforementioned California physician. The check is for \$345 for "March-Phlebotomy." VIBRANT paid the \$345 to the physician's family-member even though the family-member did not perform any blood draws.

ANSWER:

The allegations in Paragraph 38 purport to quote from or characterize Exhibit C, to which no response is required. To the extent a response is required, Vibrant admits Exhibit C appears to be a check for \$345 for "March-Phlebotomy" signed on behalf of Vibrant. Vibrant lacks information sufficient to form a belief about the remaining allegations in Paragraph 38 and therefore, to the extent a further response is required, denies the remaining allegations.

39. As previously stated, Medicare pays \$3 draw fees per patient. Here, VIBRANT pays \$15 draw fees, which it calls "Process and Handling" and "Collection" fees. This remuneration is illegal as it is intended to induce medical assistants and physicians to order laboratory tests.

ANSWER:

Vibrant admits that the reimbursement under the Medicare Fee Schedule for CPT Code 36415 (Routine Venipuncture) is \$3. Vibrant denies the remaining allegations in Paragraph 39.

40. VIBRANT's practices are an unlawful kickback scheme, strictly prohibited by the Medicare statutes and other laws, and give rise to False Claims Act liability.

ANSWER:

Denied.

41. Like the "collection" fees paid in the OIG Advisory Opinion's scenario noted above, VIBRANT's "Process and Handling" and "Collection" fees and other "compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab." OIG Advisory Opinion No. 05-08, at p. 4. The "Process and Handling" and "Collection"

fees paid by VIBRANT is many multiples of Medicare's \$3 draw fee. This alone gives rise to an inference of illegal remuneration. Moreover, as in the scenario considered by the OIG's Advisory Opinion, the "Process and Handling" and "Collection" fees provided by VIBRANT have the effect of incentivizing physicians to order more tests, creating a "risk of overutilization and inappropriate higher costs to the Federal health care programs." *See Id.* at p. 4.

ANSWER:

The allegations in Paragraph 41 constitute legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 41.

42. VIBRANT presented to Medicare and Medicaid claims for reimbursement of laboratory tests which were neither reasonable nor necessary but were ordered by physicians in exchange for kickbacks. As such, each of these claims constitutes a false claim in violation of the Federal and California False Claims Acts. VIBRANT certified, both explicitly and implicitly, that each claim it submitted to Medicare would fully comply with all statutes and regulations, and that as Medicare providers it would comply with all pertinent statutes and regulations.

ANSWER:

Denied.

VI. VIBRANT ILLEGALLY PROMISES TO CAP PATIENT CO-PAY AND DEDUCTIBLE RESPONSIBILITIES

43. In October 1994, the OIG issued a Special Fraud Alert, entitled "How Does the Anti-Kickback Statute Relate to Arrangement for the Provision of Clinical Lab Services?" (1994 Special Fraud Alert: available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.htm>.) As an example of an illegal kickback, the Special Fraud Alert cited laboratories that waive charges to providers for lab tests of managed care patients (such as the deductible and co-payments of patients here).

ANSWER:

The allegations in Paragraph 43 purport to refer to a 1994 OIG Special Fraud Alert to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 43 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the 1994 OIG Special Fraud Alert, or are incomplete recitations of such alert.

44. A significant portion of a physician's non-Medicare and non-Medicaid patients will be covered by private insurance. In recent years patient deductible amounts have escalated dramatically, with many plans having patient deductibles between \$2,000 and \$5,000.

ANSWER:

Vibrant lacks information sufficient to form a belief about the allegations in Paragraph 44 and therefore denies the same.

45. In order to induce the referral of additional business, especially government pay business, VIBRANT does not charge patients any amount in excess of \$25, regardless of the patient's responsibility. VIBRANT also agrees not to send any patients to collections, even if the \$25 is never paid. Regardless of the amount VIBRANT bills, and regardless of the amount a patient is ultimately responsible for under their insurance plan, the patient is never charged more than \$25. Even worse, VIBRANT instructs physicians to tell their patients to ignore any deductible or co-pay charges.

ANSWER:

Denied.

46. VIBRANT offers a variety of panels. Two that are frequently ordered together are the Cardiovascular and Women's Health panels. Exhibit D, attached hereto, shows the tests, CPT codes and Medicare reimbursement for these panels. Combined, the deductible costs for these panels amount to more than \$650. If additional tests are ordered, the deductible costs can exceed \$1,000. Patients on statin medication may receive up to four panels per year. An actual VIBRANT test requisition containing VIBRANT's Cardiovascular Panel is attached hereto as Exhibit E. VIBRANT

provided this requisition to the aforementioned California physician.

ANSWER:

Vibrant admits that it offers a variety of testing panels. Vibrant states that whether Cardiovascular and Women's Health panels are "frequently" ordered together is a characterization to which no response is required but, to the extent a response is required, Vibrant denies that those panels are "frequently" ordered together. The third sentence of Paragraph 46 is a characterization of Exhibit D to which no response is required. Vibrant denies the fourth and fifth sentences of Paragraph 46 and notes that Exhibit D does not purport to show deductible amounts. Vibrant is without information to form a belief as to whether to admit or deny the sixth sentence of Paragraph 46. While Exhibit E appears to be a Vibrant test requisition containing Vibrant's Cardiovascular Panel, Vibrant can neither admit nor deny the seventh sentence of Paragraph 46, including due to the poor image quality of Exhibit E. Vibrant admits it provided requisitions to physicians though, including given the preceding sentence of Vibrant's Answer, it can neither admit nor deny that it provided this particular requisition to "the aforementioned California physician."

47. After meeting their deductible obligations, most private insurance companies require that a patient make a co-payment of 20% of allowable charges for laboratory tests. This would amount to over \$130 for the combination Cardiovascular and Women's Health panels. With additional tests, the patient co-payment can exceed \$200. VIBRANT does not collect these amounts.

ANSWER:

Vibrant lacks information sufficient to form a belief as to the truth of the allegations in the first, second, and third sentences of Paragraph 47 and therefore denies the same. Vibrant denies the remaining allegations in Paragraph 47.

48. VIBRANT knows this strategy is illegal because it provides a significant benefit to a referring physician. In an effort to conceal its scheme and avoid liability, VIBRANT does not list this policy on its website. Instead, this information is communicated personally by VIBRANT Sales Representatives. In or around April of 2016, Tanja Elliott, VIBRANT's southern California Sales Representative, explained this policy

to the same southern California physician described above.

ANSWER:

Denied.

49. While VIBRANT loses money on uncollected patient deductible and co-payments, it more than makes up the difference with the profits it earns on the Medicare and Medicaid referrals from doctors, which are obtained through VIBRANT's marketing and sales kickback scams. This Medicare and Medicaid business, induced by the combination of deductible and co-payment waivers for privately insured patients and cash paid to physicians for each referral, is referred to in the industry as "pull-through" business

ANSWER:

Denied.

50. VIBRANT's policy and practice of capping or waiving patient co-pays and/or deductibles and its policy and practice of refusing to send patients to collections violate the Federal and California False Claims Acts.

ANSWER:

Denied.

VII. VIBRANT'S KICKBACK SCHEMES ALSO VIOLATE THE CALIFORNIA INSURANCE FRAUDS PROTECTIONS ACT

51. VIBRANT's capping or waiving of patient co-pays and/or deductibles, its refusal to send patients to collections, and its payment of \$15 draw fees to physicians' family and staff members also violate the California Insurance Code. Pursuant to California Insurance Code § 1871.7(a), it is "unlawful to knowingly employ runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits . . . or to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis of a claim against an insured individual or his or her insurer." As noted earlier, Section 1871.7(a) has been construed as prohibiting charging private insurers for services procured via

kickbacks.

ANSWER:

Vibrant denies the allegations in the first sentence of Paragraph 51. The remaining allegations in Paragraph 51 are legal conclusions and characterizations to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 51 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the California Insurance Code, or are incomplete recitations of such law.

52. Like the Federal False Claims Act, any person or entity that violates § 1871.7(a) is subject to a civil penalty of up to \$10,000 for each claim submitted to an insurer for payment. The person or entity is also subject to treble damages for the amount of the claim for compensation billed to the insurer.

ANSWER:

The allegations in Paragraph 52 are legal conclusions to which no response is required. To the extent a response is required, Vibrant denies the allegations in Paragraph 52 to the extent that they are inconsistent with the text of, or are Relator's interpretation of, the California Insurance Code and False Claims Act, or are incomplete recitations of such laws.

53. VIBRANT's \$15 draw fees, its capping and waiving of co-pays and deductibles, and its refusal to send patients to collections for failure to pay the \$25 dollar deductible or co- payment are fraudulent kickback schemes. VIBRANT's fraudulent kickback schemes violate California Insurance Code § 1871.7(a) because they cause VIBRANT's sales representatives to act as "runners, cappers, steerers, or other persons" to procure physicians (i.e., "clients"), who in turn perform tests "that will be the basis of a claim against an insured individual or his or her insurer." (Cal. Ins. Code § 1871.7). These violations subject VIBRANT to treble damages for the amount of the claim for compensation billed to the insurer.

ANSWER:

Denied.

VIII. CAUSES OF ACTION

FIRST CAUSE OF ACTION

On Behalf of the United States

Federal False Claims Act, Presenting False Claims

31 U.S.C. § 3729(a)(1)(A)

54. Relator incorporates by reference and realleges all of the allegations contained in paragraphs 1 through 53 of this Complaint as though fully set forth herein.

ANSWER:

Vibrant incorporates by reference its answers to the allegations in Paragraphs 1 through 53.

55. Defendant knowingly (as defined in 31 U.S.C. § 3729(b)(1)) caused to be presented false claims for payment or approval to an officer or employee of the United States.

ANSWER:

Denied.

56. Defendant knowingly caused to be presented false records and statements, including but not limited to bills, invoices, requests for reimbursement, and records of services, in order to obtain payment or approval of charges by the Medicare, Medicaid, and other government-funded programs that were higher than they were permitted to claim or charge by applicable law. Among other things, Defendant knowingly caused the submission of false claims for Medicare, Medicaid, and other government programs' business that was obtained by means of, and as a result of, illegal kickbacks.

ANSWER:

Denied.

57. The conduct of Defendant violated 31 U.S.C. § 3729(a)(1)(A) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

ANSWER:

Denied.

SECOND CAUSE OF ACTION

On Behalf of the United States

**Federal False Claims Act, Making or Using False Records or Statements Material to Payment or
Approval of False Claims**

31 U.S.C. § 3729(a)(1)(B)

ANSWER:

58. Relator incorporates by reference and realleges all of the allegations contained in paragraphs 1 through 53 of this Complaint as though fully set forth herein.

ANSWER:

Vibrant incorporates by reference its answers to the allegations in Paragraphs 1 through 53.

59. Defendant knowingly (as defined in 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

ANSWER:

Denied.

60. Defendant knowingly made, used, and/or caused to be made and used false records and statements, including but not limited to bills, invoices, requests for reimbursement, and records of services, that were material to the payment or approval of charges by the Medicare, Medicaid, and other government programs that were higher than they were permitted to claim or charge by applicable law. Among other things, Defendant knowingly caused the submission of false claims for Medicare, Medicaid, and other government programs' business that was obtained by means of, and as a result of, illegal kickbacks.

ANSWER:

Denied.

61. Defendant knowingly made, used, and caused to be made and used false certifications that its claims, and all documents and data upon which those claims were based, were accurate, and were supplied in full compliance with all applicable statutes and

regulations.

ANSWER:

Denied.

62. The conduct of Defendant violated 31 U.S.C. § 3729(a)(1)(B) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

ANSWER:

Denied.

THIRD CAUSE OF ACTION

On Behalf of the State of California

**California Insurance Frauds Prevention Act, Employment of Runners, Cappers and Steerers or
Other Persons to Procure Patients**

Cal. Ins. Code § 1871.7(a)

63. Relator incorporates by reference and realleges all of the allegations contained in paragraphs 1 through 53 of this Complaint as though fully set forth herein.

ANSWER:

Vibrant incorporates by reference its answers to the allegations in Paragraphs 1 through 53.

64. Pursuant to California Insurance Code §1871.7(a), it is unlawful to knowingly employ runners, cappers, steerers, or other persons to procure patients for the purpose of submitting a claim to that patient's insurance carrier.

ANSWER:

Denied.

65. Defendant unlawfully incentivized physicians by paying illegal remuneration for the purpose of procuring more physicians to order tests, which were ultimately submitted to Medicare, Medicaid, other government programs, and private insurance companies for reimbursements, in violation of Cal. Ins. Code §1871.7(a).

ANSWER:

Denied.

1 **66. Because the claims submitted to medical insurers by Defendant were procured by**
2 **runners, cappers, and steerers and other persons, these claims were false and**
3 **fraudulent under the California Insurance Frauds Prevention Act.**

4 **ANSWER:**

5 Denied.

6 **67. This conduct was a substantial factor causing damages detailed herein.**

7 **ANSWER:**

8 Denied.

9 **FOURTH CAUSE OF ACTION**

10 **On Behalf of the State of California**

11 **California Insurance Frauds Prevention Act, Presenting or Causing to be Presented False or**
12 **Fraudulent Claims for the Payment of An Injury Under A Contract of Insurance**

13 **Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(1)**

14 **68. Relator incorporates by reference and realleges all of the allegations contained in**
15 **paragraphs 1 through 53 of this Complaint as though fully set forth herein.**

16 **ANSWER:**

17 Vibrant incorporates by reference its answers to the allegations in Paragraphs 1 through 53.

18 **69. Defendant has caused to be presented false and fraudulent claims for reimbursement**
19 **of tests, or conspired to present or cause to be presented such false and fraudulent**
20 **claims.**

21 **ANSWER:**

22 Denied.

23 **70. These claims were fraudulent because:**

- 24 • Defendant caused the submission of claims to Medicare, Medicaid, other
25 government programs, and private insurers for medically unnecessary and
26 unreasonable tests.
- 27 • Defendant caused the submission of claims for reimbursement for tests that were
28 procured by means of, or otherwise involved, the payment of illegal kickbacks.

ANSWER:

Denied.

71. Defendant either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

ANSWER:

Denied.

72. This conduct was a substantial factor causing damages detailed herein.

ANSWER:

Denied.

FIFTH CAUSE OF ACTION

On Behalf of the State of California

California Insurance Frauds Prevention Act, Knowingly Preparing or Making Any Writing in Support of a False or Fraudulent Claim

Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(5)

73. Relator incorporates by reference and realleges all of the allegations contained in paragraphs 1 through 53 of this Complaint as though fully set forth herein.

ANSWER:

Vibrant incorporates by reference its answers to the allegations in Paragraphs 1 through 53.

74. Defendant has either knowingly prepared, made, or subscribed a writing with an intent to present or use it, or to allow it to be presented, in support of false and fraudulent claims for the reimbursement of tests performed on patients, or has aided, abetted, and solicited, or conspired to make, or subscribe such a writing.

ANSWER:

Denied.

75. These writings include bills for payment presented to insurance carriers for payment, and invoices prepared in support of such bills for payment. Such bills for payment constitute false or fraudulent claims because through those bills:

- Defendant caused the submission of claims to Medicare, Medicaid, other

government programs, and private insurers for medically unnecessary and unreasonable tests.

- Defendant caused the submission of claims for reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks.

ANSWER:

Denied.

76. Defendant either directly presented such false claims for payment to insurers, or caused such false claims to be presented.

ANSWER:

Denied.

77. This conduct was a substantial factor causing damages detailed herein.

ANSWER:

Denied.

SIXTH CAUSE OF ACTION

On Behalf of the State of California

California Insurance Frauds Prevention Act, Knowingly Making or Causing to be Made Any

False or Fraudulent Claim for Payment of a Health Benefit

Cal. Ins. Code § 1871.7(b); Cal. Pen. Code § 550(a)(6)

78. Relator incorporates by reference and realleges all of the allegations contained in paragraphs 1 through 53 of this Complaint as though fully set forth herein.

ANSWER:

Vibrant incorporates by reference its answers to the allegations in Paragraphs 1 through 53.

79. Defendant has either knowingly presented or caused to be presented false and fraudulent claims for reimbursement of tests performed on patients, or has aided, abetted, and solicited, or conspired to present or cause to be presented such false and fraudulent claims.

ANSWER:

Denied.

1 **80. The claims were false or fraudulent because:**

- 2 • Defendant caused the submission of claims to Medicare, Medicaid, other
3 government programs, and private insurers for medically unnecessary and
4 unreasonable tests.
- 5 • Defendant caused the submission of claims for reimbursement for tests that were
6 procured by means of, or otherwise involved, the payment of illegal kickbacks.

7 **ANSWER:**

8 Denied.

9 **81. Defendant either directly presented such false claims for payment to insurers, or**
10 **caused such false claims to be presented.**

11 **ANSWER:**

12 Denied.

13 **82. This conduct was a substantial factor causing damages detailed herein.**

14 **ANSWER:**

15 Denied.

16 **SEVENTH CAUSE OF ACTION**

17 **On Behalf of the State of California**

18 **California False Claims Act, Presenting False Claims**

19 **California Government Code § 12651(a)(1)**

20 **83. Relator incorporates by reference and realleges all of the allegations contained in**
21 **paragraphs 1 through 53 of this Complaint as though fully set forth herein.**

22 **ANSWER:**

23 Vibrant incorporates by reference its answers to the allegations in Paragraphs 1 through 53.

24 **84. Defendant knowingly (as defined in California Government Code section 12650,**
25 **subdivision (b)(2)), presented or caused to be presented false claims for payment or**
26 **approval to an officer or employee of California.**

27 **ANSWER:**

28 Denied.

85. Defendant knowingly caused to be presented claims for payment or approval for services that were procured by means of illegal kickbacks.

ANSWER:

Denied.

86. The conduct of Defendant violated Government Code section 12651, subdivision (a)(1), and caused California to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

ANSWER:

Denied.

EIGHTH CAUSE OF ACTION

On Behalf of the State of California

California False Claims Act, Making Or Using

False Records Or Statements

To Obtain Payment Or Approval Of False Claims

California Government Code § 12651(a)(2)

87. Plaintiff incorporates by reference and realleges all of the allegations contained in paragraphs 1 through 53 of this Complaint as though fully set forth herein.

ANSWER:

Vibrant incorporates by reference its answers to the allegations in Paragraphs 1 through 53.

88. Defendant knowingly (as defined in California Government Code section 12650, subdivision (b)(2)), made, used, or caused to be made or used false records or statements to get false claims paid or approved by California.

ANSWER:

Denied.

89. Defendant knowingly made, used, and/or caused to be made and used false records and statements, including but not limited to claims, bills, invoices, requests for reimbursement, and records of services, in order to obtain payment or approval of charges to the Medi-Cal program for services that were procured by illegal kickbacks.

ANSWER:

Denied.

90. The conduct of Defendant violated Government Code section 12651, subdivision (a)(2), and caused California to sustain damages in an amount according to proof pursuant to Government Code section 12651, subdivision (a).

ANSWER:

Denied.

PRAYER FOR RELIEF

Vibrant incorporates by reference its answers to Paragraphs 1 through 90 and deny that Relator is entitled to the relief set forth in the PRAYER FOR RELIEF paragraphs immediately following Paragraph 90, identified as 91(a) through (e) and 92, or to any relief whatsoever. Vibrant further denies each and every allegation not previously admitted or otherwise qualified.

AFFIRMATIVE DEFENSES

Without admitting any of the allegations in the First Amended Complaint, Vibrant asserts and alleges the following Affirmative Defenses to the claims and allegations set forth in Relator's First Amended Complaint and reserves the right to seek leave to amend or supplement these Defenses as discovery and further investigation warrant.

First Affirmative Defense

The First Amended Complaint and every purported action therein alleged fails to state facts sufficient to constitute a claim upon which relief may be granted.

Second Affirmative Defense

Relator's claims are barred because Vibrant did not violate the False Claims Act, California False Claims Act, California Insurance Frauds Prevention Act, or Anti-Kickback Statute.

Third Affirmative Defense

Relator's claims are barred because Relator's theories underlying the First Amended Complaint and its alleged causes of action are incorrect as a matter of law including but not limited to because Vibrant did not violate the Anti-Kickback Statute.

Fourth Affirmative Defense

Relator's claims are barred in whole or in part because Vibrant has at all times acted in good faith and not with any improper or illegal purpose, and Vibrant therefore did not act with the intent necessary to constitute a violation under any cause of action.

Fifth Affirmative Defense

Relator's claims are barred in whole or in part because Vibrant at all times complied with applicable legal standards, regulations, rules, and agency guidance.

Sixth Affirmative Defense

Relator's claims are barred in whole or in part because Vibrant did not act "knowingly" as that term is defined in 31 U.S.C. § 3729(b)(1); California Government Code § 12651(a); nor California Penal Code § 550.

Seventh Affirmative Defense

Relator's claims are barred in whole or in part because Vibrant did not knowingly present or cause to be presented a false or fraudulent claim for payment or approval.

Eighth Affirmative Defense

Relator's claims are barred in whole or in part because Vibrant did not knowingly make, use, or caused to be made or used, a false record or statement material to a false or fraudulent claim.

Ninth Affirmative Defense

Relator's claims are barred in whole or in part by reason of the fact that Relator's claims do not relate to conduct by Vibrant that is material for False Claims Act or California False Claims Act liability or otherwise.

Tenth Affirmative Defense

Relator's claims are barred in whole or in part by reason of the fact that Vibrant did not knowingly employ runners, cappers, steerers, or other persons to procure clients within the meaning of the California Insurance Frauds Prevention Act or otherwise.

Eleventh Affirmative Defense

Relator's claims are barred in whole or in part by reason of the fact that Vibrant did not knowingly present or caused to be presented a false or fraudulent claim for payment or approval by a private insurer.

Twelfth Affirmative Defense

Relator's claims are barred in whole or in part because Vibrant did not knowingly prepare, make or subscribe any writing, with the intent to present or use it, or allow it to be presented in support of a false or fraudulent claim for payment or approval by a private insurer.

Thirteenth Affirmative Defense

Relator's claims are barred in whole or in part because Vibrant did not knowingly make or caused to be made a false or fraudulent claim for payment or approval by a private insurer.

Fourteenth Affirmative Defense

Relator's claims are barred because of Relator's or a member of Relator's role in the purported conduct.

Fifteenth Affirmative Defense

Relator's claims are barred because of Relator's or a member of Relator's unclean hands and failure to act in good faith.

Sixteenth Affirmative Defense

Relator's theories underlying the First Amended Complaint and its alleged causes of action are incorrect as a matter of law because they are based on non-binding regulatory and sub-regulatory guidance.

Seventeenth Affirmative Defense

Relator's claims are barred in whole or in part because Relator's claims are vexatious, frivolous, and intended only to annoy, embarrass, and harass Vibrant.

Eighteenth Affirmative Defense

The First Amended Complaint and each purported claim for relief therein is barred, in whole or in part, by the fact that the United States has not suffered any actual injury and/or damages

Nineteenth Affirmative Defense

Relator's recovery, if any, should be barred or reduced because of the application of 31 U.S.C. § 3730(d)(3) to its member's own actions in planning and initiating any alleged violations of section 3729.

Twentieth Affirmative Defense

Relator's recovery, if any, should be barred or reduced because of the application of California Government Code § 12652(g)(5) to its member's own actions in planning and initiating any alleged

violations of section 12650.

Twenty-First Affirmative Defense

The First Amended Complaint, to the extent it seeks damages and/or penalties above and beyond actual damages, is unconstitutional because such damages and/or penalties would violate the Fifth and Eighth Amendments to the United States Constitution.

Additional Affirmative Defenses

Vibrant reserves the right to assert additional defenses as the litigation proceeds, and to amend its defenses to conform to the facts and pleadings developed in the course of this case.

PRAYER FOR RELIEF

WHEREFORE, Vibrant prays for relief as follows:

1. That Relator, the United States and the State of California are not entitled to any relief and take nothing by the First Amended Complaint;
2. That the Court enter judgment in Vibrant's favor and dismiss Relator's claims in their entirety;
- and
3. For such other relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Vibrant demands a trial by jury on all issues so triable.

Dated: October 19, 2020

FOLEY & LARDNER LLP

Thomas S. Brown

Judith A. Waltz

Lori A. Rubin

/s/ Thomas S. Brown

Thomas S. Brown

Attorneys for Defendant

VIBRANT AMERICA, LLC

CERTIFICATE OF SERVICE

I hereby certify that on October 19, 2020, pursuant to Local Rule 5-1 and Federal Rule of Civil Procedure 5(b), that the foregoing document was filed electronically with the Clerk of the Court using the CM/ECF and served upon counsel of record.

Dated: October 19, 2020

By: /s/ Thomas S. Brown